CDC INSTITUTIONAL REVIEW BOARD (IRB)
HUMAN SUBJECTS ADVERSE EVENTS REPORT

(TO BE FILLED OUT BY LEAD **CDC** INVESTIGATOR)

Date Received in HSA:	**Protocol No.:**

Instructions: Use this form when submitting adverse event reports for IRB review. In order to facilitate rapid processing, please submit this form electronically to your CIO HSC. However, if submitting hard copies, please send the original & two copies of your documentation to HSA through your HSC. Complete all applicable items or the form will be returned.

CDC defines three categories of adverse events (AE):

1. Anticipated Adverse Events (AAE) - The HSA & the CDC IRBs recognize that in many of the research studies in which CDC is involved, investigators will encounter anticipated adverse events (e.g., deaths of AIDS patients who may be participating in HIV/AIDS research studies) that should be reported to the IRB & to OHRP. CDC's policy is to require investigators to notify the IRB of these events at the time of the annual continuing review.

2. Unanticipated Adverse Events (UAE) - CDC defines an unanticipated adverse event as an unforeseen problem involving risks to subjects or others encountered during the conduct of any research study in which CDC is involved. Unanticipated adverse events that should be reported to the CDC IRB include, but are not limited to: (1) physical injury to a participant; (2) psychological, social, or economic harm to a participant; (3) breaches of protocol, such as breakdowns in the informed consent process, violations of confidentiality of data or privacy of a participant, & complaints by participants or their representatives; & (4) any serious or continuing noncompliance with federal regulations by investigators or research staff. These events should be reported in writing on the CDC Human Subjects Adverse Event Report form (0.1257) within 15 days of the CDC investigator's discovery of the event. UAEs do ***NOT*** include clearly unrelated events (e.g., injuries sustained in a car accident while on the way to the study site).

3. Serious Unanticipated Adverse Events (SUAE) - CDC defines serious unanticipated adverse events as those that are life threatening and/or represent significant, immediate risk to the study participant or others. These events should be reported to the CIO HSC (and appropriate others within the CIO) within 7 days of the event. The CIO HSC should subsequently notify the HSA by telephone of the event within the next 48 hours. Upon reporting the event to the CIO HSC within 7 days of the investigator's discovery of the event & the reporting of the event to the HSA within the next 48 hours, investigators should submit a written report of the event within 15 working days, as described above.

The CIO HSC will inform the CDC HSA of the UAE or SUAE. After CDC IRB review of the event, the HSA will inform the CDC investigator of the outcome of the CDC IRB review, either through a memorandum indicating that the IRB has reviewed the report, found the actions taken appropriate, & that no further action is required, or in the form of a CDC IRB report that outlines the IRB's concerns & requests. Upon resolution of the event, HSA will notify the CDC DADS of the event & actions taken, who will then notify OHRP in writing of the event.

Protocol Title:		
Name of Primary CDC Contact :		**Degrees:**
***Scientific Ethics* Verification No.:**		**CDC User ID:**
CIO:	**Division:**	**MS:**
Telephone:		**FAX:**

Date of AE:	**Participant's I.D. Number (if available):**
Name of Drug, Device or Procedure (if applicable)	**Date AE became known to you:**

Describe in detail the nature & timing of the AE (attach addendum if necessary):

The likelihood that the event was caused by the study is (definitions given at the end of form):

_____ Definite **_____ Unlikely**

_____ Probable **_____ Not related**

_____ Possible **_____ Unclassifiable**

Describe in detail the impact (e.g., participant died, required follow-up treatment or prolonged hospitalization, participant remains on study, etc.) of the AE on the current study procedure:

Describe in detail any corrective actions (e.g., stopped enrollment of new participants, halted study, changed data management/coding procedures, formed committee to review procedures, etc.) that have been taken to date:

To whom has this event been reported (check all that apply):

_____ Co-investigator **_____ FDA**

_____ Local IRB **_____ DMC**

As a result of this AE, does the protocol need revision?	**As a result of this AE, does the informed consent document need revision?**
_____ YES	**_____ YES**
_____ NO	**_____ NO**

If yes, please submit amendment (CDC form 0.1252), revised protocol and/or consent form.

Approvals/Signatures:	**Date:**	**Remarks:**
I hereby accept responsibility for conducting this CDC-sponsored research project in an ethical manner, consistent with the policies & procedures contained in CDC's "Procedures for Protection of Human Research Participants"& to abide by the principles outlined in 45 CFR 46, "Protection of Human Subjects."		
Investigator:		
Branch Chief:		
Division Director:		
CIO HS Contact:		

Definitions (modified FDA definitions):

Definite: Events occurring within a timely manner after administration of the interaction/intervention that are known sequelae of the interaction/intervention & follow a previously documented pattern but for which no other explanation is known. This category applies to those AEs that the investigator believes are incontrovertibly related to the interaction/intervention.

Probable: Any event occurring in a timely manner after administration of the interaction/intervention that follows a known pattern of reaction to the interaction/intervention & for which no other explanation is known. This category applies to those AEs that, after careful medical consideration at the time they are evaluated, are believed with a high degree of certainty to be related to the interaction/intervention.

Possible: Any event occurring in a timely manner after administration of the interaction/intervention that does not follow a known pattern of reaction & for which no other explanation is known. This category applies to those AEs that, after careful medical consideration at the time they are evaluated, are considered to be unlikely to be related but cannot be ruled out with certainty.

Unlikely: In general, this category can be considered applicable to those AEs that, after careful medical consideration at the time they are evaluated, are considered to be unrelated to administration of the interaction/intervention.

Not related: Any AE for which there is evidence that an alternative etiology exists or for which no timely relationship exists to the administration of the interaction/intervention & the AE does not follow any previously documented pattern. This category applies to those AEs that, after careful medical consideration, are clearly & incontrovertibly due to causes other than the interaction/intervention.

Unclassifiable: There is insufficient information about the AE to allow for an assessment of causality.